

Food and Drug Administration, HHS

§ 520.1660d

agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsidered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

§ 520.1660c Oxytetracycline hydrochloride tablets/boluses.

(a) *Specifications.* Each tablet or bolus contains 250, 500, or 1,000 milligrams of oxytetracycline hydrochloride.

(b) *Sponsors.* For sponsors in § 510.600(c) of this chapter: See 000010 for use of 500 and 1,000 milligram boluses. See 000069 for use of 250 and 500 milligram tablets.

(c) *Tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in beef and dairy cattle*—(1)(i) *Amount.* 250 milligrams per 100 pounds of body weight every 12 hours (5 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use.* For control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(2)(i) *Amount.* 500 milligrams per 100 pound of body weight every 12 hours (10 milligrams per pound of body weight daily in two doses).

(ii) *Indications for use.* For treatment of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida*.

(3) *Limitations.* Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily). For sponsor 000069: Discontinue treatment 7

days prior to slaughter. Not for use in lactating dairy cattle.

[46 FR 32440, June 23, 1981, as amended at 50 FR 1045, Jan. 9, 1985; 63 FR 70334, Dec. 21, 1998]

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) *Specifications.* The drug is a soluble powder distributed in packets or pails having several concentrations of oxytetracycline hydrochloride (independent of the various net weights) as follows:

(1) Each 18.14 grams of powder contains 1 gram of oxytetracycline hydrochloride (OTC HCl) (packets: 4, 6.4, and 16 oz.).

(2) Each 4.43 grams of powder contains 1 gram of OTC HCl (packets: 4 and 16 oz.).

(3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz; pail: 3.09 lb).

(5) Each 4.2 grams of powder contains 1 gram of OTC HCl (packets: 3.8 and 15.2 oz; pails: 4.74 and 23.7 lb).

(6) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 oz.).

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

(8) Each 135.5-gram packet (4.78 ounce) contains 102.4 grams of OTC HCl. Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.75 oz; pails: 5 lb).

(b) *Sponsor.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 000069 for use of OTC HCl concentrations in paragraphs (a)(1), (a)(2), and (a)(3) of this section in chickens, turkeys, swine, cattle, sheep, and honey bees.

(2) No. 046573 for use of OTC HCl concentration in paragraph (a)(4) of this

section in chickens, turkeys, and swine.

(3) No. 000010 for use of OTC HCl concentration in paragraph (a)(5) of this section in turkeys and chickens.

(4) No. 057561 for use of OTC HCl concentration in paragraph (a)(6) of this section in chickens, turkeys, and swine.

(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, and sheep.

(6) No. 053389 for use of OTC HCl concentrations in paragraph (a)(8) of this section in chickens, turkeys, swine, cattle, and sheep.

(7) No. 061133 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use.* (1) It is used in drinking water as follows:

(i) *Chickens—(A)(1) Amount per gallon.* 200 to 400 milligrams.

(2) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(B)(1) *Amount per gallon.* 400 to 800 milligrams.

(2) *Indications for use.* Control of chronic respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption.

(ii) *Turkeys—(A)(1) Amount per gallon.* 200 to 400 milligrams.

(2) *Indications for use.* Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(B)(1) *Amount per gallon.* 400 milligrams.

(2) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(C)(1) *Amount.* 25 milligrams per pound of body weight.

(2) *Indications for use.* Growing turkeys. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

(3) *Limitations.* Prepare a fresh solution daily. Administer 7 to 14 days. Not to be used for more than 14 consecutive days. Use as sole source of drinking water. Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 046573, 057561, and 059130 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 000010. Zero-day withdrawal for those products sponsored by No. 053389.

(iii) *Swine—(A) Amount.* 10 milligrams per pound of body weight daily.

(B) *Indications for use.* Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia

caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Use as sole source of OTC. Administer up to 14 days; do not use for more than 14 consecutive days; withdraw 5 days prior to slaughter those products sponsored by Nos. 000069 and 059130. Administer up to 5 days; do not use for more than 5 consecutive days; withdraw 13 days prior to slaughter those products sponsored by Nos. 046573 and 057561.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 milligrams per pound of body weight daily.

(B) *Indications for use*. Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

(v) *Sheep*—(A) *Amount*. 10 milligrams per pound of body weight daily.

(B) *Indications for use*. Control and treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

(C) *Limitations*. Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Withdraw 5 days prior to slaughter.

(2) It is used in the food of honey bees as follows:

(i) *Amount*. 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture.

(ii) *Indications for use*. Control and treatment of American and European foul brood caused by *Bacillus larvae* susceptible to oxytetracycline.

(iii) *Limitations*. The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow.

[50 FR 32694, Aug. 14, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 520.1660d, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 520.1696 Penicillin oral dosage forms.

§ 520.1696a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.

(a) *Specifications*. When reconstituted, each milliliter contains penicillin G procaine equivalent to 20,000, 25,000, 40,000, 50,000, 80,000, or 100,000 units of penicillin G.

(b) *Sponsor*. [Reserved]

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use. Chickens*—It is used in drinking water as follows:

(1) *Amount*. 100,000 units per gallon.

(i) *Indications for use*. Treatment of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).

(ii) *Limitations*. As penicillin G procaine; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

(2) *Amount*. 50,000 to 100,000 units per gallon.

(i) *Indications for use*. Prevention of chronic respiratory disease (air-sac infection) and bluecomb (nonspecific infectious enteritis).